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(71) Applicant *(for all designated States except US)*: **SUNSHINE HEART COMPANY PTY LTD** [AU/AU]; 2A River Street, Birchgrove, NSW 2041 (AU).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **PETERS, William, Suttle** [NZ/NZ]; 93 Bassett Road, Remuera, Auckland 1005 (NZ). **HENRICHSEN, Hans, Hansforth** [AU/AU]; 26/21 Market Street, Wollongong, NSW 2500 (AU). **WATTERSON, Peter, Andrew** [AU/AU]; 13 Driver Street, Denistone, NSW 2114 (AU).

(74) Agent: **SPRUSON & FERGUSON**; G.P. Box 3898, Sydney, NSW 2001 (AU).

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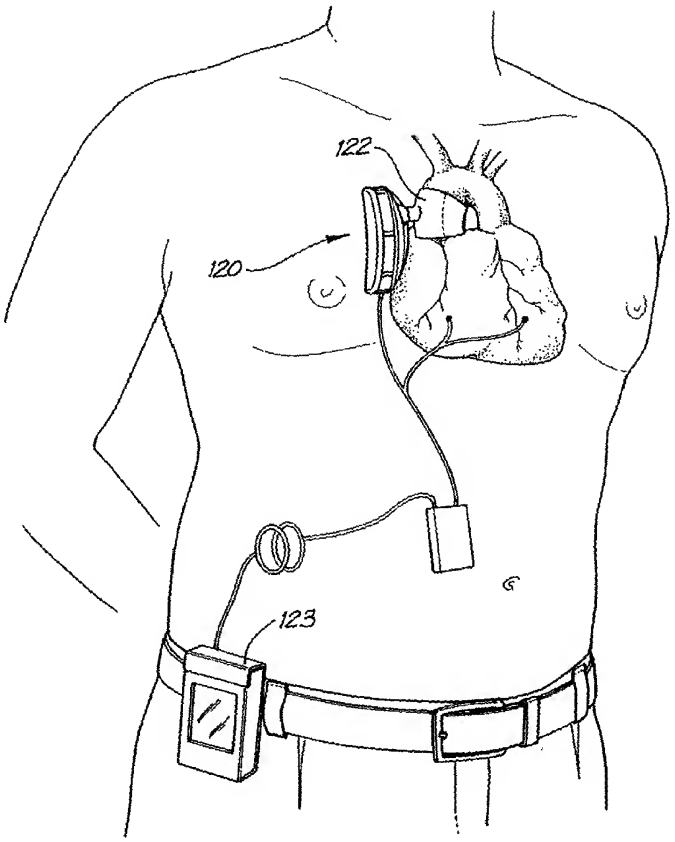
(54) Title: A FLUID PRESSURE GENERATING MEANS



(57) Abstract: A fluid pressure generating means (10) for a heart assist device having blood pumping means. The pressure generating means (10) includes a housing (11), defining an interior volume (18), and having a substantially rigid first housing portion (12), a substantially rigid second housing portion (14), a flexible third housing portion (16) extending between the first (12) and second (14) housing portions and an inlet/outlet port (15) adapted for fluid communication with the blood pumping means. The pressure generating means (10) also includes a fluid filling the housing and a motor (20) disposed within the housing (11) and connected between the first (12) and second (14) housing portions. Actuation of the motor (20) moves the first (12) and second (14) housing portions relative to one another to generate fluid pressure changes at the inlet/outlet port (15). A related heart assist device and method for the treatment of congestive heart failure, myocardial ischemia and like conditions are also disclosed.

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A Fluid Pressure Generating Means

Field of the Invention

The present invention relates to a fluid pressure generating means for use with a heart assist device.

Background of the Invention

The applicant's international PCT patent application no. PCT/AU00/00654 (International publication no. WO 00/76288) entitled "Heart Assist Devices, Systems and Methods" ("the PCT application") discloses numerous embodiments of a novel heart assist device adapted for implantation into a patient. Broadly speaking, the disclosed heart assist devices include: an aortic compression means adapted, when actuated, to compress an aorta of a patient; a fluid reservoir; and a fluid pressure generating means adapted to pump fluid from the fluid reservoir to the aortic compression means so as to actuate the aortic compression means in counterpulsation with the patient's heart. The relevant portions of the PCT application are incorporated herein by cross-reference.

It is a first object of the present invention to provide improved fluid pressure generating means suitable for use with the aortic compression means described in the PCT application. It is a second object to provide a fluid pressure generating means which may be placed more conveniently into the body of a patient.

Summary of the Invention

Accordingly, in a first aspect, the present invention provides a fluid pressure generating means for a heart assist device having blood pumping means, the pressure generating means including:

a housing, defining an interior volume, and having a substantially rigid first housing portion, a substantially rigid second housing portion, a flexible third housing portion extending between the first and second housing portions and an inlet/outlet port adapted for fluid communication with the blood pumping means;

a fluid filling the housing; and

a motor or other actuator means disposed within the housing and connected between the first and second housing portions,

wherein actuation of the motor or other actuator means moves the first and second housing portions relative to one another to generate fluid pressure changes at the inlet/outlet port.

In one preferred form, the third housing portion has an outer edge about its periphery and inner edge about an opening and is joined along the outer and the inner edge to the first and second housing portions respectively.

In another preferred form, the third housing portion is connected to only one of the first and second housing portions and abuts against the other of the first and second housing portions.

The blood pumping means is preferably adapted to displace blood in the aorta, more specifically the ascending aorta, and preferably by compressing or deforming the aorta of a patient in counter-pulsation with the patient's heart. More preferably, the blood pumping means is adapted to displace blood from the ascending aorta of the patient. In an alternative arrangement, the fluid pressure generating means can be used to drive a conventional left ventricular assist device or an extra-ventricular co-pulsation heart compression device. In such an arrangement suitable valves are used to ensure the correct direction of blood flow through a pumping chamber driven by the fluid pressure generating means.

In a further preferred form, one of the first and second housing portions is moveable and the other of the first and second housing portions is fixed, the moveable housing portion being exposed to the outside of the heart assist device and adapted to interface with the lung of a patient.

In a yet further preferred form, one of the first and second housing portions is moveable and the other of the first and second housing portions is fixed, the moveable housing portion not being exposed to the outside of the heart assist device and the device including a flexible compliance chamber. The compliance chamber is desirably in contact with the lung of a patient.

The actuating means desirably includes a nut coupled to one of the first and second housing portions and a threaded shaft coupled to the other of the first and second housing portions, the threaded shaft and the nut being threadedly engaged and the motor being adapted to rotate the nut relative to the threaded shaft. In one arrangement, the nut is connected to the moveable one of the first and second housing portions and the threaded shaft is connected to the fixed one of the first and second housing portions. In another arrangement, the threaded shaft is connected to the moveable one of the first and second housing portions and the nut is connected to the fixed one of the first and second housing portions.

In an embodiment, the outflow of the fluid from the inlet/outlet port is axial to the housing. In another embodiment, the outflow of the fluid from the inlet/outlet port is radial to the housing. In a further embodiment, the outflow of the fluid from the inlet/outlet port is tangential to the housing.

A surface of the device is preferably curved to fit snugly with the chest wall and/or mediastinum and/or diaphragm of a patient.

The blood pumping means is preferably in the form of a fluid operated cuff adapted to surround the patient's aorta.

The fluid filling the housing is preferably a liquid. The liquid is preferably an oil or saline. The oil is preferably a silicone oil and desirably has viscosity between 10 and 100 centistokes, most desirably between 10 and 30 centistokes.

In a second aspect, the present invention provides a heart assist device including:

a blood pumping means adapted, when actuated, to cause or assist the movement of blood around the patient's vasculature;

a fluid reservoir;

a fluid pressure generating means adapted to pump fluid from the fluid reservoir to the blood pumping means; and

a housing containing both the fluid reservoir and the fluid pressure generating means that is so shaped and dimensioned as to be adapted to lie in the plueral cavity, adjacent to the lung, when the blood pumping means is functionally positioned within the patient.

In a third aspect, the present invention provides a method for the treatment of congestive heart failure, myocardial ischemia and like conditions, the method comprising:

inserting into the plueral cavity within the chest (preferably the right chest) of a patient, and adjacent to the lung, a housing containing a fluid reservoir and a fluid pressure generating means adapted to pump fluid from the fluid reservoir to blood pumping means functionally placed in the patient so as to cause or assist the movement of blood around the patient's vasculature.

Until now most implanted heart assist devices have been placed in the abdominal cavity of a patient. This is disadvantageous as it complicates the surgical procedure and is unduly invasive for the patient. The few proposals for placement of such a device in the chest cavity have proposed the placement of the device against the inside of the chest wall so that the device can be wired to the ribs of the patient. It was apparently felt that this was necessary to support the weight of the device and to prevent it from moving

around in the patient. The present inventors have found that the device may be placed against the mediastinum directly adjacent the patient's heart and attached to surrounding soft tissue. The device will thus lie in the plueral cavity, adjacent to the lung. The device preferably lies in a sagittal plane within the patient's body. Desirably, the device will not touch the inside surface of the chest wall at all. This placement will reduce pain for the patient and make placement of the device easier for the surgeon implanting the device.

Preferably, the blood pumping means referred to in the above method is adapted to compress the aorta of a patient in counter-pulsation with the patient's heart. More preferably, the blood pumping means is adapted to compress the ascending aorta of the patient.

In a fourth aspect, the present invention provides a heart assist device including:

a blood pumping means adapted, when actuated, to cause or assist the movement of blood around the patient's vasculature;

a fluid reservoir; and

a fluid pressure generating means driven by an electric motor and adapted to pump a liquid from the fluid reservoir to the blood pumping means;

the electric motor having a cogging torque which is sufficiently low that the natural systolic blood pressure of the patient is sufficient to cause liquid in the blood pumping means to be returned to the fluid reservoir in the event that the electric motor stops.

Brief Description of the Drawings

Preferred embodiments of the invention will now be described, by way of examples only, with reference to the accompanying drawings in which:

Fig. 1 is a schematic longitudinal sectional view of a first embodiment of a fluid pressure generating means according to the invention;

Fig. 2 is a schematic longitudinal sectional view of a second embodiment of a fluid pressure generating means according to the invention;

Fig. 3 is a schematic longitudinal sectional view of a third embodiment of a fluid pressure generating means according to the invention connected to a heart assist device;

Fig. 4a is a perspective view of a fourth embodiment of a fluid pressure generating means according to the invention;

Fig. 4b is an underside perspective view of a housing portion of the fluid pressure generating means shown in Fig. 4a;

Fig. 4c is a schematic longitudinal sectional view of the fluid pressure generating means shown in Fig. 4a; and

Fig. 5 is a schematic longitudinal sectional view of a fifth embodiment of a heart assist device according to the invention;

Fig. 6 is a perspective view of the device shown in Fig. 5; and

Fig. 7 is a perspective view of the device shown in Fig. 6 after implantation into the pleural cavity, medial to the lung, of a patient.

Detailed Description of the Preferred Embodiments

Referring firstly to Fig. 1, there is shown a schematic longitudinal sectional view of a first embodiment of a fluid pressure generating means according to the invention, in the form of pump 10. The pump 10 includes a housing, indicated generally by the reference numeral 11, comprising a substantially rigid bell-shaped first housing portion 12, a substantially rigid flat circular second housing portion 14 and a flexible third housing portion or membrane 16.

The first, second and third housing portions 12, 14 and 16 together define an external boundary of the housing 11 around an interior volume denoted 18, which is filled with a silicone oil. The second housing portion 12 is itself formed from a cone-shaped portion 12a which is sealingly connected, after assembly of the pump 10, to a cylindrical portion 12b.

The cone-shaped portion 12a also includes an inlet/outlet port 15, which is connected in fluid communication with an aortic compression means or blood pumping means (not shown) by a conduit 17.

The membrane 16 is substantially annular in configuration and has enlarged inner and outer edges 16a and 16b which are sealingly received in corresponding circumferential recesses 12c and 14a provided in the first and second housing portions 12 and 14 respectively.

The pump 10 also includes an electric motor, indicated generally by the reference numeral 20, within the interior volume 18 of the housing 11. The motor includes a rotor 21, rotor laminations 22, magnets 24, stator 25, stator laminations 26, end windings 28 and bearings 30.

The stator 25 is fixed to the housing portion 12a by a number of screws 30 (only one shown). The rotor 21 is fixed to a nut 32, which is itself threadedly engaged with a threaded shaft 34 through ball bearings (not shown). The shaft 34 is fixed to the housing

portion 14 by screw 36. The stator 25 also includes a number of guide journals 38 (only one shown) through which are guided a corresponding number of shafts 40 that depend from the housing portion 14.

Power and control signals are fed to the motor 20 through lines 42 and 44 respectively.

The operation of the pump 10 will now be described. Energising the motor 20 to rotate in a first direction rotates the nut 32 relative to the threaded shaft 34 which causes the threaded shaft 34 to move in a direction parallel to its longitudinal axis in a first direction indicated by arrow 46. Fig. 1 shows the shaft 34 at the end of its travel in this direction and after driving the housing portion 14 away from the housing portion 12 to increase the interior volume 18 and cause a suction or negative pressure at the inlet/outlet port 15. This suction actively deflates the aortic compression means (not shown).

Energising the motor to rotate in the opposite direction causes the threaded shaft 34 to move parallel to the longitudinal axis in the opposite direction indicated by arrow 48 and draw the portion 14 towards the housing portion 12. The end limit of travel in this direction is indicated in phantom in Fig. 1 and, with reference to which it should be noted that, the guide shaft 40 abuts the inner surface of the housing portion 12a at the limit of its travel at recess 50. Drawing the flexible portion 14 towards the housing portion 12 reduces the interior volume 18 which causes a positive pressure at the inlet/outlet port 15 and drives fluid from the interior volume 18 to inflate the aortic compression means.

The motor 20 is actuated cyclicly in this manner in counterpulsation with the patient's heart in response to signals received from an ECG monitor or systemic arterial pressure, as disclosed in the PCT application.

Referring now to Fig. 2, there is shown a schematic longitudinal sectional view of a second embodiment of a fluid pressure generating means according to the invention, in the form of pump 60. The pump 60 is similar to the pump 10 shown in Fig.1 and like features are indicated with like reference numerals. Differences between the pumps 10 and 60 are described in detail below.

Firstly, the housing portion 12a of the pump 60 includes an opening 62 sealed by a second flexible membrane 64 which forms a compliance chamber 65. The chamber 65 is in fluid communication with the interior volume 18. Secondly, the inlet/outlet port 15 is provided in a further housing portion 66 which is sealed with respect to the side of the second housing portions 14 and third housing portion 16 that is remote the motor 20. The housing portion 66 creates, in conjunction with the housing portions 14 and 16, a second

interior volume 68 in fluid communication with the aortic compression means or blood pumping means (not shown) via conduit 17.

The operation of the pump 60 is similar to that as described with reference to the pump 10 with the exception that the movement of the housing portion 14 causes volume changes in the second interior volume 68 which in turn inflates and deflates the aortic compression means. The movement of the housing portion 14 also causes fluid movement in the part of the interior volume 18 within the first, second and third housing portions 12, 14 and 16 and these changes cause an identical volume change in the interior of the compliance chamber 65, which is shown having a decreased volume in response to the compression means being inflated. The chamber 65 will have an increased volume in response to the compression means being deflated, as is shown in phantom.

As the interior volumes 18 and 68 are maintained sealed from one another by the second and third housing portions 14 and 16, the pump 60 can be configured to use different fluids in each of the interior volumes 18 and 60, as desired. For example, a saline solution can be used in the interior volume 68 and a lubricating oil can be used in the interior volume 18 which contains the motor 20.

Fig. 3 is a schematic cross sectional side view of a third embodiment of a fluid pressure generating means according to the invention, in the form of pump 80. The pump 80 is shown connected to an aortic compression means or blood pumping means in the form of cuff 82. The pump 80 is similar to the pump 60 described in relation to Fig. 2 and like reference numerals will be used to indicate like features. Differences between the pumps 60 and 80 are described in detail below.

Firstly, the pump 80 has a first external substantially rigid cylindrical housing portion 84, a pair of second internal substantially rigid housing portions 86a and 86b and a third substantially flexible housing portion 88. The latter seals an end of the first housing portion 84. The pump 80 also includes a second flexible housing portion 90 which seals the other end of the second housing portion 84 and forms a compliance chamber 92. Secondly, the second housing portion 86 and the third flexible housing portion 88 abut, but are not connected, to each other.

The operation of the pump 80 is similar to that described with reference to pump 60 in that the motor 20 is energised to reciprocally drive the threaded shaft 34 and thus the second housing portion 86a in directions 46 and 48 parallel to the longitudinal axis of the threaded shaft 34.

Fig. 3 shows the pump 80 in a position after movement of the second housing portion 86a in the direction 46 and driving fluid from the second interior volume 68 into the cuff 82 to inflate same. In this position, the second membrane of 64 is drawn into the interior of the second housing portion 84 to maintain the interior volume 18 constant. Driving the threaded shaft 34 in the opposite direction 48 results in the housing portion 86b forcing the membrane 64 to the position shown in phantom which is external the second housing portion 84. This also results in the third housing portion 88 being drawn to the position also shown in phantom to maintain the interior volume 18 constant. As previously described in relation to pump 60, when the third housing portion 86 is in this position fluid is drawn into the second interior volume 68 from the cuff 82 to deflate same.

Figs. 4A to 4C show a fourth embodiment of a fluid pressure generating means according to the invention, in the form of pump 100. The pump 100 is similar to the pump 10 shown in Fig. 1 and like components have been referred to with like reference numerals. However, the pump 100 has been designed to be as thin as possible (dimensions: 82 mm long; 60 mm wide; and 45 mm deep) in order to allow positioning in a patient's chest in contact with the mediastinum adjacent the heart. The pump 100 is placed with the planar housing portion 14 lying in a sagittal plane and with the edge of the housing 100 clear of the inside surface of the chest wall. This orientation is chosen so as to minimise pain and trauma to the patient and also minimise the length of conduit required between the pump 100 and the aortic compression means (not shown). This positioning also assists the surgeon in placing the device.

Referring finally to Figs. 5 to 7, there is shown a schematic longitudinal sectional view of a fifth embodiment of a fluid pressure generating means according to the invention in the form of pump 120. The pump 120 is shown connected to an aortic compression means or blood pumping means in the form of cuff 122. The construction and operation of the pump 120 is similar to the pump 10 shown in Fig. 1 and like features are indicated with like reference numerals. The size of the pump 120 is similar to the pump 100 shown in Figs. 4A to 4C, except it is more ovate and has flattened sides (See Fig. 6). The ovate form of the pump 120 and the positioning of the cuff 122 nearer one end allows the device to be placed in the plural cavity, medial to the lung, and lying in a sagittal plane within the patient's body, as is shown in Fig. 7. The pump 120 does not touch the inside surface of the patient's chest wall in this position. Fig. 7 also shows an external battery pack 123 which powers the pump 120.

The main differences between the pumps 10 and 120 are as follows. Firstly, the flexible third housing portion 16 is sealingly connected about its outer edge 16b to the substantially rigid ovate cup-shaped first housing portion 12. The connection and sealing is achieved by a sealing rim 124 on the third portion 16 being snugly received in an annular recess 126 on the first portion 12. Secondly, the substantially rigid flat ovate second housing portion 14 is received within a corresponding recess in the third portion 16, on the interior side of the third portion 16, and is thus within the interior volume 18.

Fig. 5 shows the pump 120 in a position after movement of the second housing portion 14 in the direction 46, which draws fluid into the interior volume 18 from the cuff 122 and deflates same. Driving the threaded shaft 34 in the opposite direction 48 forces the second housing portion 14 towards the motor 20 (see the position of the shaft 34 shown in phantom). As previously described, when this occurs, fluid is forced from the interior volume 18 into the cuff 82 to inflate same.

An advantage of the preferred embodiments of fluid pressure generating means described above is the liquid surrounding the motor is used both as a driving fluid to inflate/deflate the compressions (either directly as per the embodiments of Figs. 1 and 4 or indirectly as per the embodiment of Figs. 2 and 3) and as a cooling/lubricating/heat exchanging fluid. The liquid also dampens sound made by the pump mechanism. This simplifies the construction, and minimises the size, of the fluid pressure generating means.

Whilst the fluid pressure generating means will normally actively drive both the inflation and deflation of the aortic compression means, the motor is preferably designed so that the cogging torque of the motor is sufficiently low that the natural systolic blood pressure of the patient is sufficient to deflate the cuff. If the motor is inactivated for any reason with the cuff in an inflated condition (and thus with the aorta partially occluded), this arrangement means that the natural systolic blood pressure will deflate the cuff by pushing fluid from the cuff into the housing and passively driving the second housing portion away from the motor.

It will be appreciated by person skilled in the art that numerous variations and/or modifications can be made to the invention as shown in the specific embodiments without departing from the spirit or scope of invention as broadly described. For example, the embodiments of the invention are not restricted for use with the embodiments of the heart assist device shown in the PCT application. The specific embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

Claims:

1. A fluid pressure generating means for a heart assist device having blood pumping means, the pressure generating means including:

a housing, defining an interior volume, and having a substantially rigid first housing portion, a substantially rigid second housing portion, a flexible third housing portion extending between the first and second housing portions and an inlet/outlet port adapted for fluid communication with the blood pumping means;

a fluid filling the housing; and

a motor or other actuator means disposed within the housing and connected between the first and second housing portions,

wherein actuation of the motor or other actuator means moves the first and second housing portions relative to one another to generate fluid pressure changes at the inlet/outlet port.

2. The fluid pressure generating means as claimed in claim 1, wherein the third housing portion has an outer edge about its periphery and inner edge about an opening and is joined along the outer and the inner edge to the first and second housing portions respectively.

3. The fluid pressure generating means as claimed in claim 1, wherein the third housing portion is connected to only one of the first and second housing portions and abuts against the other of the first and second housing portions.

4. The fluid pressure generating means as claimed in claim 1, 2 or 3, wherein the blood pumping means is adapted to displace blood from the aorta of a patient in counter-pulsation with the patient's heart.

5. The fluid pressure generating means as claimed in claim 4, wherein the blood pumping means is adapted to displace blood from the ascending aorta of the patient.

6. The fluid pressure generating means as claimed in claim 1, 2 or 3, wherein the fluid pressure generating means is adapted to drive a conventional left ventricular assist device or an extra-ventricular co-pulsation heart compression device.

7. The fluid pressure generating means as claimed in any one of claims 1 to 5, wherein one of the first and second housing portions is moveable and the other of the first and second housing portions is fixed, the moveable housing portion being exposed to the outside of the heart assist device and adapted to interface with the lung of a patient.

8. The fluid pressure generating means as claimed in any one of claims 1 to 5, wherein one of the first and second housing portions is moveable and the other of the first

and second housing portions is fixed, the moveable housing portion not being exposed to the outside of the heart assist device and the device including a flexible compliance chamber.

9. The fluid pressure generating means as claimed in claim 8, wherein the compliance chamber is in contact with the lung of a patient.

10. The fluid pressure generating means as claimed in any one of the preceding claims, wherein the actuating means includes a nut coupled to one of the first and second housing portions and a threaded shaft coupled to the other of the first and second housing portions, the threaded shaft and the nut being threadedly engaged and the motor being adapted to rotate the nut relative to the threaded shaft.

11. The fluid pressure generating means as claimed in claim 10, wherein the nut is connected to the moveable one of the first and second housing portions and the threaded shaft is connected to the fixed one of the first and second housing portions.

12. The fluid pressure generating means as claimed in claim 10, wherein the threaded shaft is connected to the moveable one of the first and second housing portions and the nut is connected to the fixed one of the first and second housing portions.

13. The fluid pressure generating means as claimed in any one of the preceding claims, wherein the outflow of the fluid from the inlet/outlet port is axial to the housing.

14. The fluid pressure generating means as claimed in any one of claims 1 to 12, wherein the outflow of the fluid from the inlet/outlet port is radial to the housing.

15. The fluid pressure generating means as claimed in any one of claims 1 to 12, wherein the outflow of the fluid from the inlet/outlet port is tangential to the housing.

16. The fluid pressure generating means as claimed in any one of the preceding claims, wherein a surface of the device is curved to fit snugly with the chest wall or mediastinum of a patient.

17. The fluid pressure generating means as claimed in any one claims 1 to 5 or 7 to 16, wherein the aortic compression means is in the form of a fluid operated cuff adapted to surround the patient's aorta.

18. The fluid pressure generating means as claimed in any one of the preceding claims, wherein the fluid filling the housing is a liquid.

19. The fluid pressure generating means as claimed in claim 18, wherein the liquid is an oil or saline.

20. The fluid pressure generating means as claimed in claim 19, wherein the oil is a silicone oil.

21. The fluid pressure generating means as claimed in claim 20, wherein the oil has a viscosity between 10 and 100 centistokes.

22. The fluid pressure generating means as claimed in claim 21, wherein the oil has a viscosity between 10 and 30 centistokes.

23. A heart assist device including:

a blood pumping means adapted, when actuated, to cause or assist the movement of blood around the patient's vasculature;

a fluid reservoir;

a fluid pressure generating means adapted to pump fluid from the fluid reservoir to the blood pumping means; and

a housing containing both the fluid reservoir and the fluid pressure generating means that is so shaped and dimensioned as to be adapted to lie in the plueral cavity, adjacent to the lung, when the blood pumping means is functionally positioned within the patient.

24. A method for the treatment of congestive heart failure, myocardial ischemia and like conditions, the method comprising:

inserting into the plueral cavity within the chest of a patient, and adjacent to the lung, a housing containing a fluid reservoir and a fluid pressure generating means adapted to pump fluid from the fluid reservoir to blood pumping means functionally placed in the patient so as to cause or assist the movement of blood around the patient's vasculature.

25. The method as claim in claim 24, wherein the housing and fluid pressure generating means are inserted into the plueral cavity within the right chest of the patient.

26. The method as claimed in claim 24 or 25, wherein the device is placed against the mediastinum directly adjacent the patient's heart and attached to surrounding soft tissue.

27. The method as claimed in any one of claims 24 to 26, wherein the device is placed to lie in a sagittal plane within the patient's body.

28. The method as claimed in any one of claims 24 to 27, wherein the device is placed to lie without touching the inside surface of the chest wall at all.

29. The method as claimed in any one of claims 24 to 28, wherein the blood pumping means is adapted to displace blood in the aorta of a patient in counter-pulsation with the patient's heart.

30. The method as claimed in claim 29, wherein the blood pumping means is adapted to displace blood in the ascending aorta of the patient.

31. A heart assist device including:

a blood pumping means adapted, when actuated, to cause or assist the movement of blood around the patient's vasculature;

a fluid reservoir; and

a fluid pressure generating means driven by an electric motor and adapted to pump a liquid from the fluid reservoir to the blood pumping means;

the electric motor having a cogging torque which is sufficiently low that the natural systolic blood pressure of the patient is sufficient to cause liquid in the blood pumping means to be returned to the fluid reservoir in the event that the electric motor stops.

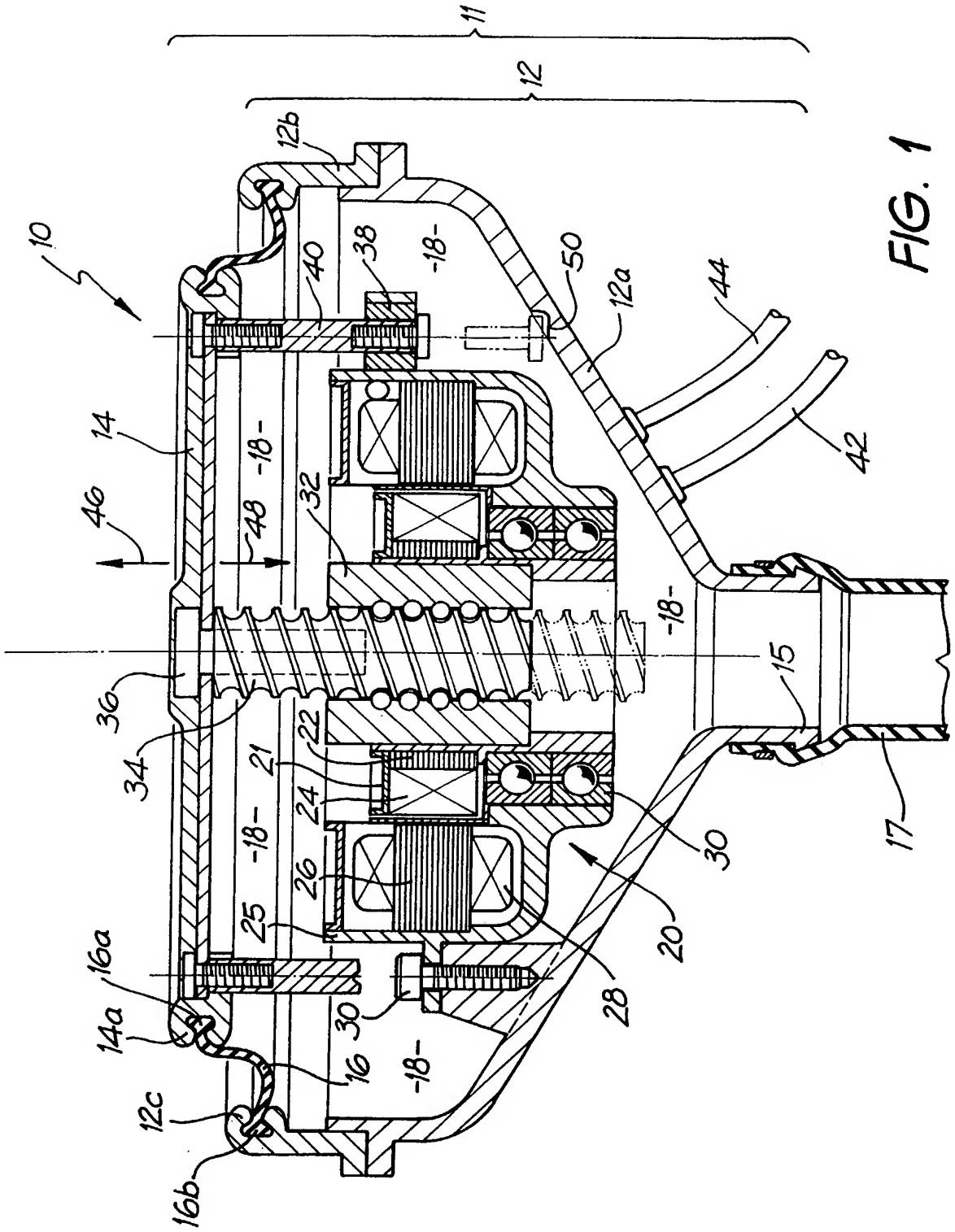
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FIG. 1

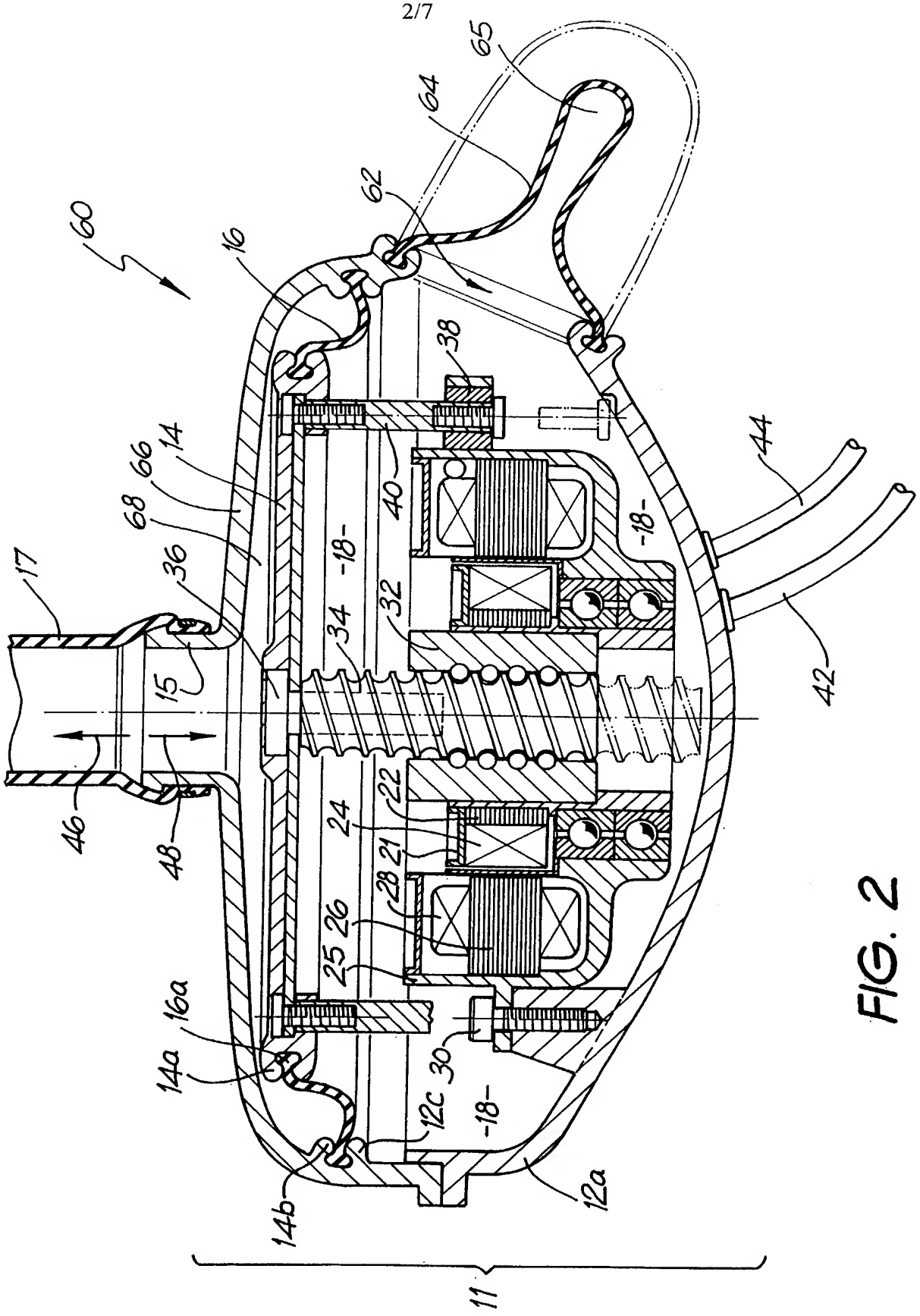
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FIG. 2

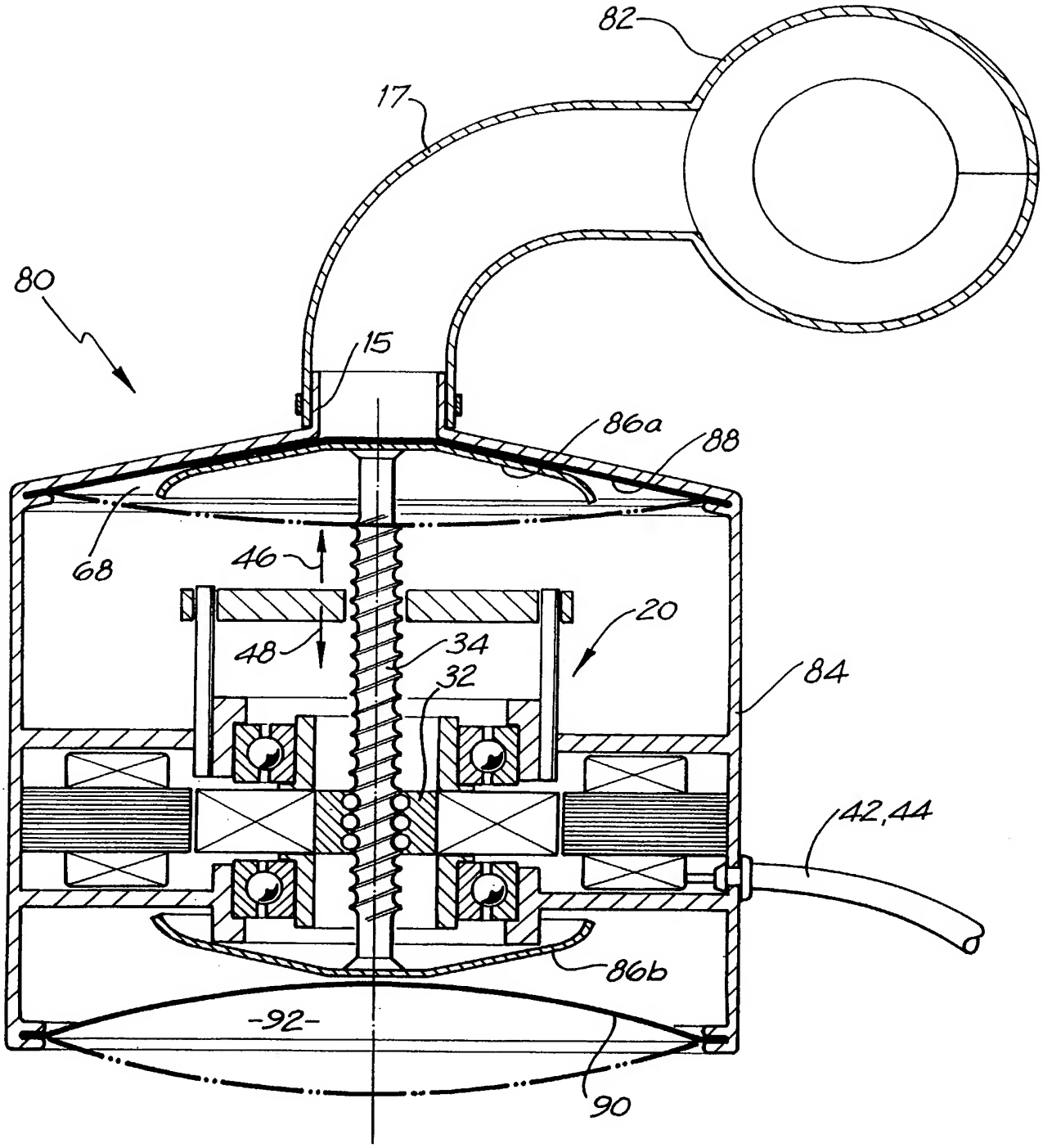


FIG. 3

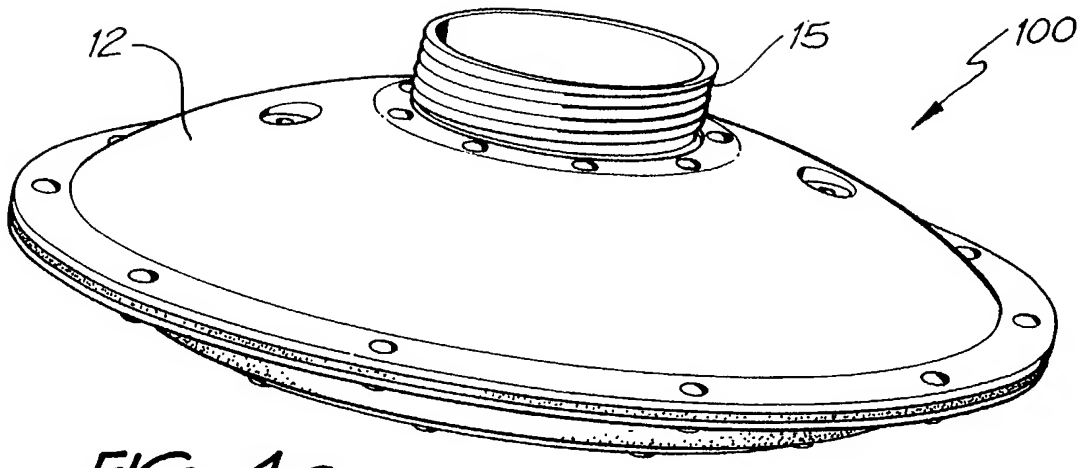


FIG. 4a

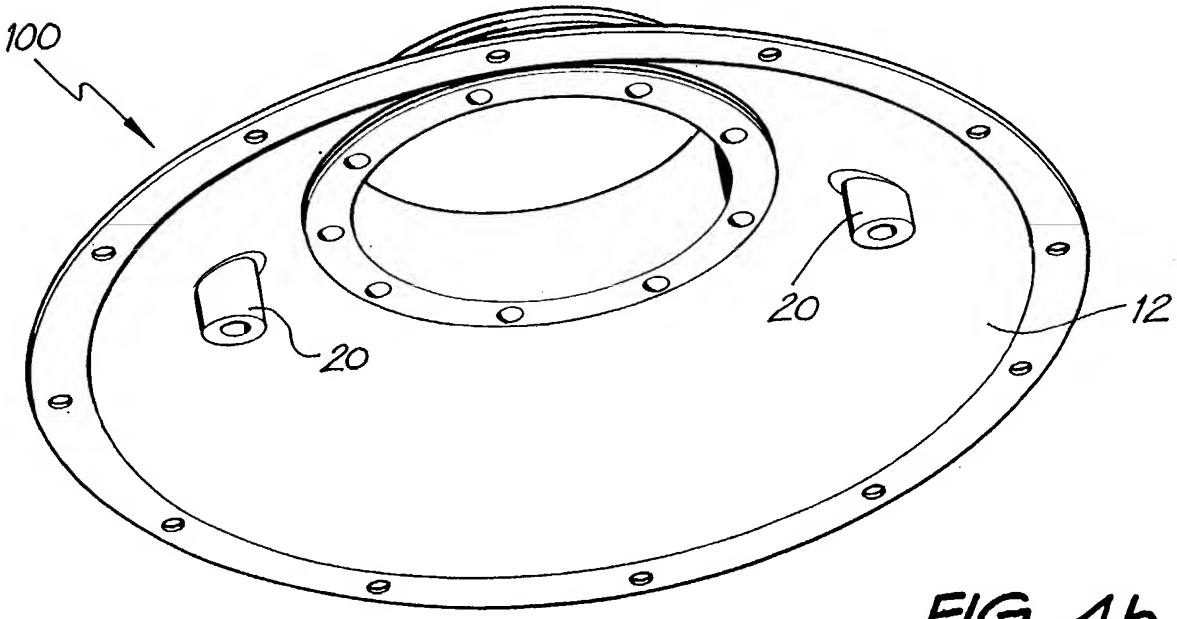


FIG. 4b

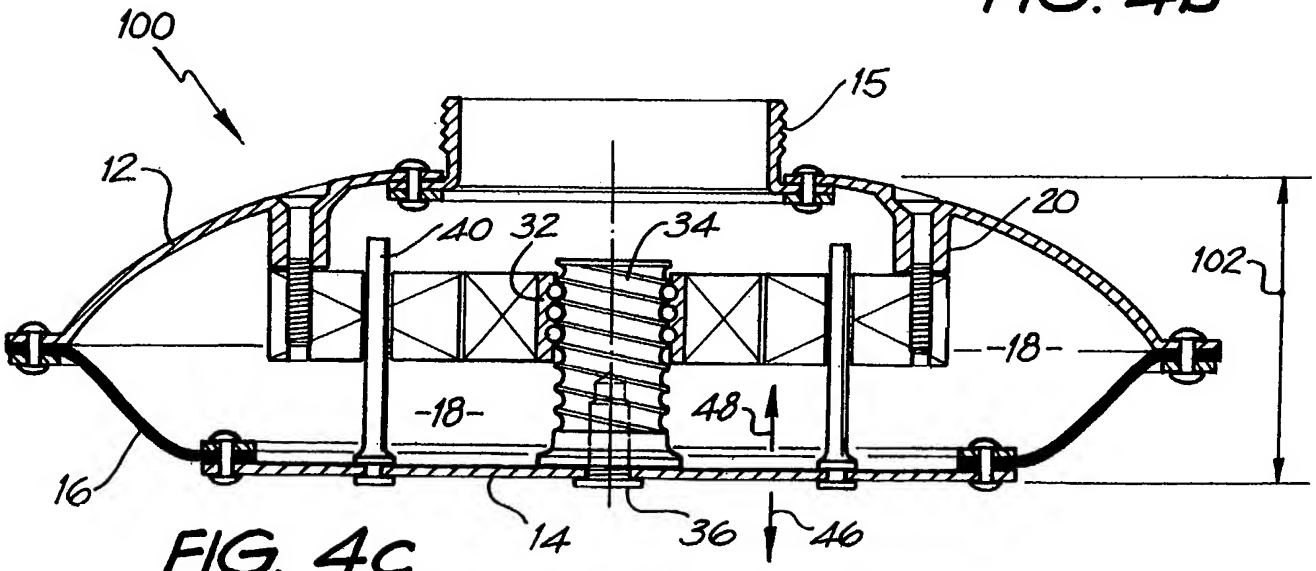
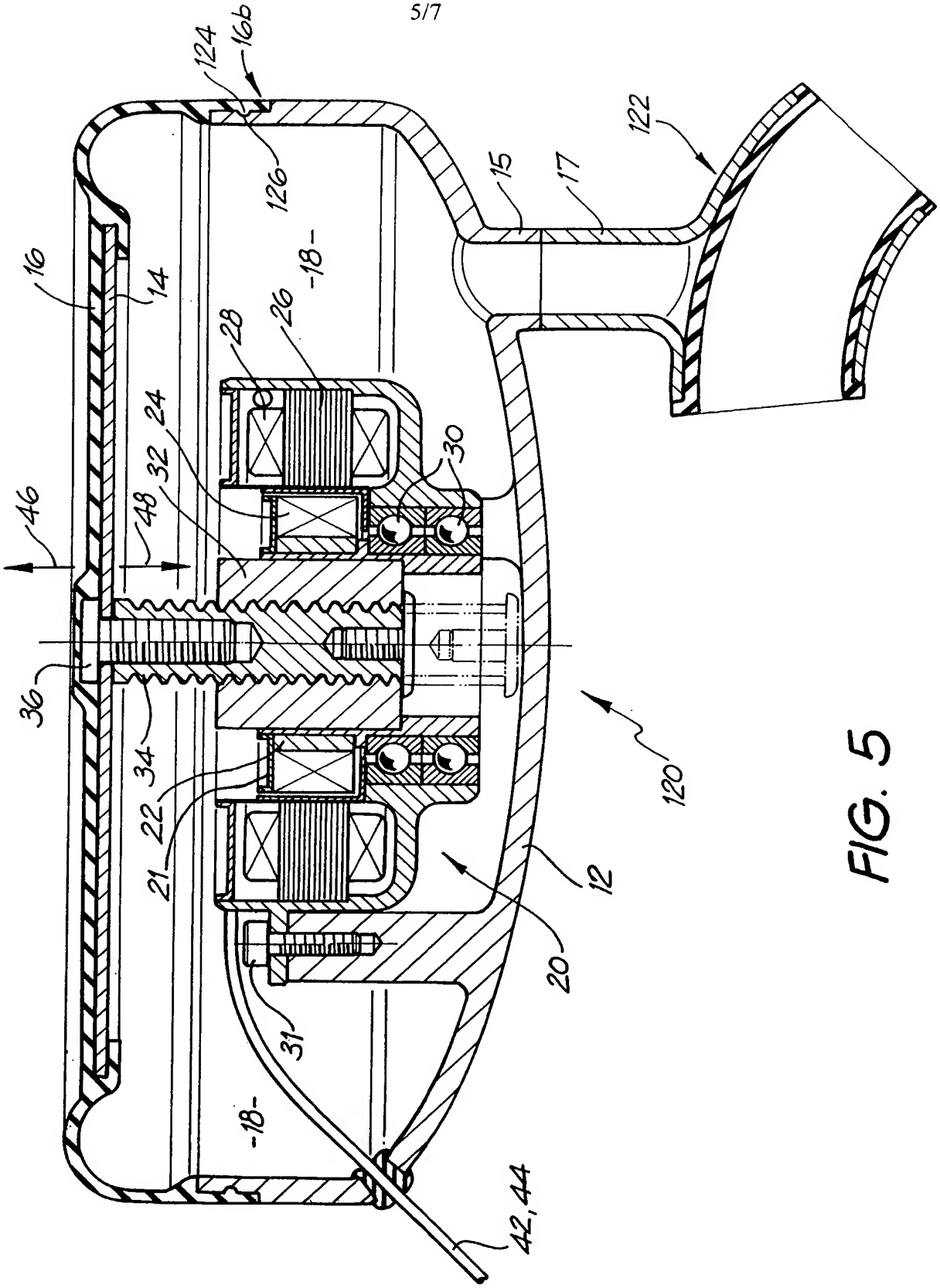


FIG. 4c


124
166
126
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31
-18-
42, 44

FIG. 5

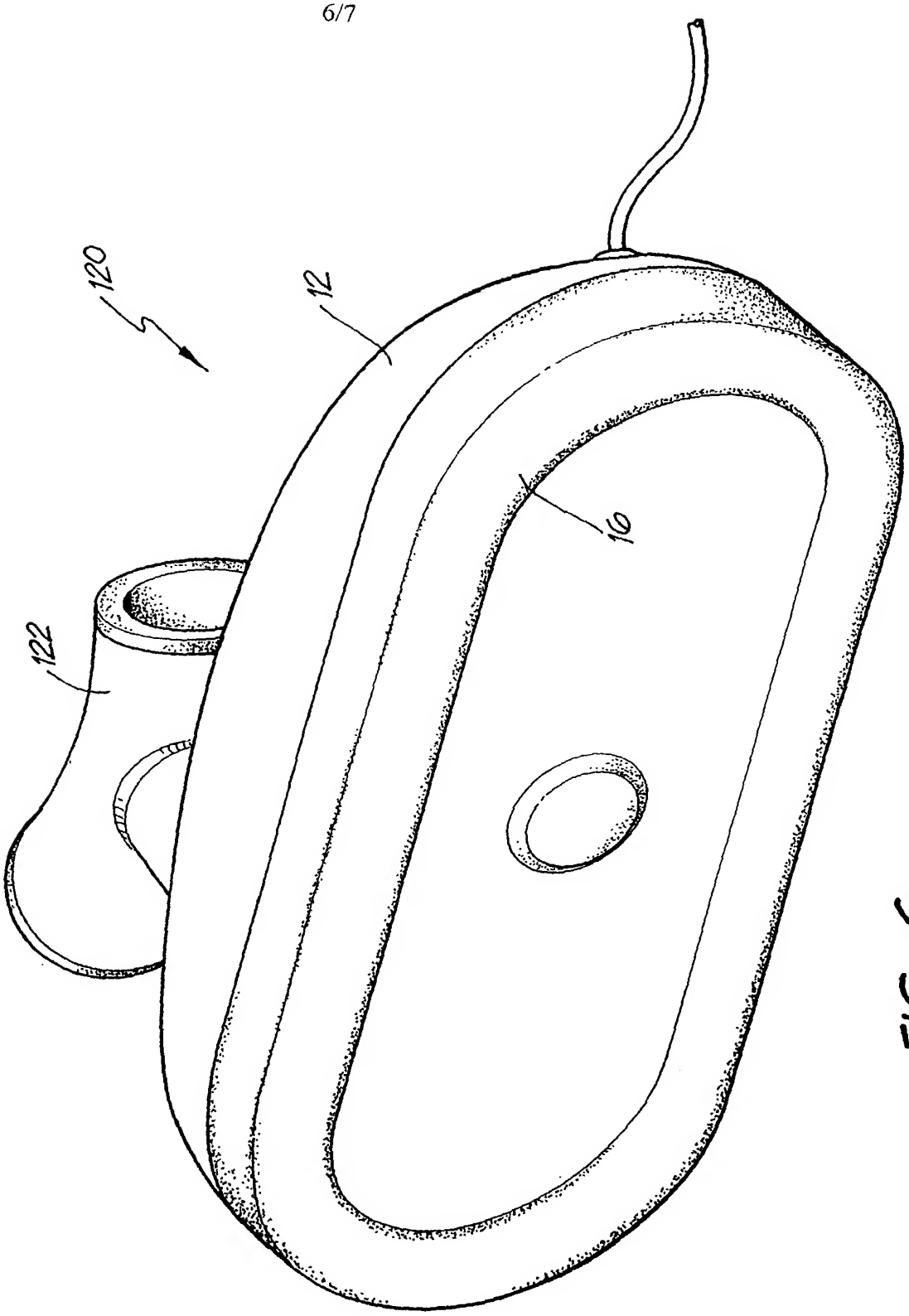

FIG. 6

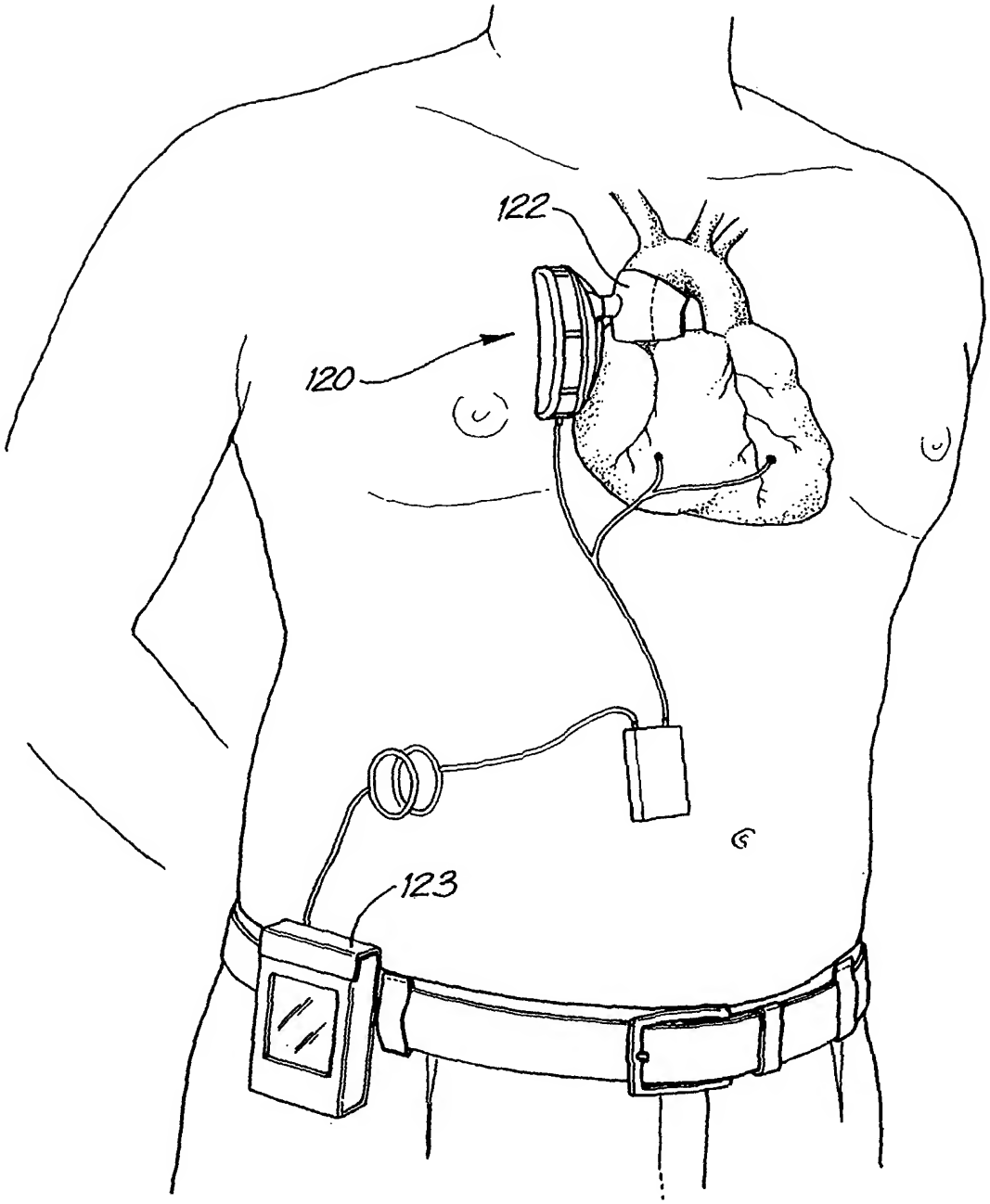

FIG. 7

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU02/00974

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. [7]: A61M 1/12, F15B 3/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
Refer electronic database consulted below

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
DWPI: keywords: 1st invention: heart aorta diaphragm cuff fluid pressure, 2nd invention: pleural thoracic, 3rd invention: failsafe cog and similar terms

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X, Y	US 6 030 336 A (FRANCHI) 29 February 2000 column 2 lines 30 to 63, column 7 lines 10 to 16, column 3 lines 35 to 39	1-8, 10-13, 18-22
A	abstract column 8 lines 27 to 30	1-30 31
X	FR 2 767 874 A1 (COMMISSARIAT ENERGIE ATOMIQUE) 5 March 1999 see English abstract	1
A	abstract	1-31
Y	US 4 277 706 A (ISAACSON) 7 July 1981 figures 1 and 2	1-3

[X] Further documents are listed in the continuation of Box C [X] See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
9 October 2002	11 OCT 2002
Name and mailing address of the ISA/AU	Authorized officer
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	**SUE THOMAS** Telephone No : (02) 6283 2454

International application No. PCT/AU02/00974		
C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	FR 2 458 288 A1 (BELENGER) 2 January 1981 figure 2	1-3
A	WO 99/04833 A1 (COMMISSARIAT ENERGIE ATOMIQUE) 4 Febuary 1999 see English abstract	1-31
A	Patent abstacts of Japan JP, 10-3228297 A (BUAAYU:KK) 15 December 1998 whole document	1-31
A	US 5 222 980 A (GEALOW) 29 June 1993 column 3 line 10 to column 5 line 32	1-31
A	WO 00/76288 A2 (SUNSHINE HEART CO.) 21 December 2000 page 4 line 5 to page 6 line 18	1-31

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU02/00974

Box I Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos :

because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos :

because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos :

because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box II Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Claims 1-22
Claims 23-30
Claim 31

(Continued on supplemental sheet)

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: 1-22

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☒ No protest accompanied the payment of additional search fees.

Supplemental Box
(To be used when the space in any of Boxes I to VIII is not sufficient)

Continuation of Box No: II

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Searching Authority has found that there are different inventions as follows:

1. Claims 1-22 are directed towards a fluid pressure generating means for a heart assist device. It is considered that the housing defining an interior volume having a rigid first portion, a rigid second portion and a flexible third portion and an inlet/outlet port comprises a first "special technical feature".

2. Claims 23-30 are directed towards a heart assist device characterised by the shape and location of the device. It is considered that the housing having a fluid reservoir and fluid generating means that is so shaped as to lie in the pleural cavity comprises a second "special technical feature".

3. Claim 31 is directed towards a heart assist device characterised by a fluid pressure generating means driven by an electric motor with sufficiently low cogging torque such that the natural systolic pressure is sufficient to cause liquid in the blood pumping means to return to the fluid reservoir in the event that the motor stops. It is considered that a mechanism for the patients circulatory system to cause liquid in the blood pumping means to return to the reservoir in the event that the electric motor stops comprises a third "special technical feature".

It is noted that the specification has admitted there are numerous systems for heart assist devices (page 1 lines 5 to 14) including an aortic compression means, a fluid reservoir, a means adapted to pump fluid from the reservoir to the aortic compression means in counterpulsation with the heart. Therefore a heart assist device with these said features cannot be considered to be special technical features in the present inventions. When a claim does not avoid the prior art, its features cannot constitute "special technical features" for the purpose of assessing commonality of invention between claims. Refer to rule 13.2 of the PCT regulations for further explanation.

Since the abovementioned groups of claims do not share any of the technical features identified, a "technical relationship" between the inventions, as defined in PCT rule 13.2 does not exist. Accordingly the international application does not relate to one invention or to a single inventive concept, *a priori*.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/AU02/00974

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
US	6030336	EP	959912	FR	2744924	WO	9730740
FR	2767874	NONE					
US	4277706	NONE					
FR	2458288	NONE					
WO	9904833	FR	2766373				
US	5222980	AU	25764/92	EP	605544	WO	9305827
WO	200076288	AU	200050548	BR	200011464	EP	1185319

END OF ANNEX